DIVISION OF HEALTH
AND MEDICAL SERVICES

Community Health Services
Disease Prevention
Family Health
Health Promotion
State Epidemiologist

MEMORANDUM 2008-10

TO: All Vaccine Providers

FROM: Tim Heath
Immunization Program Coordinator

DATE: 11/10/2008

RE: 2009 Provider Profile, Rotavirus, Hib, Flu

Dear Vaccine Providers:

It is that time of year again when the new contract needs to be signed and returned to us. I am enclosing a copy of the contract and an envelope you can use to send back to Pierre. To prevent delays in vaccine shipment, please return the completed signed original form by December 12. You can use the Immunization Registry to get the dose data used to fill out part C and D on the first page. Please follow the steps below.

1) Login to the SDIIS
2) Click on Print Reports
3) Select the Doses Administered Report
4) Click on Generate
5) From date: 11/01/2007
6) To Date: 11/01/2008
7) **Uncheck** the Vaccine field, by clicking in the box
8) Check the **VFC Eligibility Field by clicking in the box**
9) Click on submit
10) Use the data from the report to complete parts C and D

Effective December 1 the state will begin to offer Rotarix, a Rotavirus vaccine made by GlaxoSmithKline. Rotarix is a two dose series which is administered orally at 2 and 4 months. Please see the enclosed ACIP Provisional Recommendations for use of this vaccine and its interchangeability with the RotaTeq vaccine. You may also get more information from http://www.rotarix.com/. Copies of the new vaccine order form and eligibility chart are enclosed. We will still continue to offer Merck's Rotavirus vaccine, RotaTeq.

I would also like to request that if you have excess flu vaccine that you don't anticipate using, to please transfer the vaccine back to the state in Pierre. If you

need shipping materials such as coolers, ice packs, and temperature monitors; please contact Summer at 605-773-4963 or by email at Summer.Falzerano@State.SD.US. Instructions to ship refrigerated vaccines can be found in your policies and procedures manual. We will redistribute the vaccine to facilities that will be able to use it.

We are still in the midst of a Hib shortage. I would like to remind you to please submit your orders by the 5th of your ordering month. All vaccine orders that contain Hib will be placed on the first working day after the 5th. I have enclosed a document which contains some Hib Vaccine Shortage talking points. Providers do have an opportunity to order their own supply of Hib and Pentacel from Sanofi Pasteur. Please contact Jamie Redmer at James.Redmer@sanofipasetur.com or at 763-498-2288 for more information. I would also like to remind you that McKesson may take up to three weeks to deliver vaccines. Please keep enough vaccine on hand to cover this potential three week delivery time.

In addition to Hib, we are now offering Pentacel which is a DTaP/Polio/Hib combo vaccine. This vaccine is also on allocation so we have a limited supply. Below are some comments from the CDC about Pentacel:

- Pentacel is supplied as a box containing 5 vials of liquid DTaP/IPV vaccine and 5 vials of lyophilized Hib vaccine. The vaccine component should be kept together in the original box until one vial of each component is removed, reconstituted, and administered. The combined vaccine must be used within 30 minutes of reconstitution.

- Pentacel should always be used as a combination vaccine. The liquid DTaP/IPV vaccine should be used only to reconstitute the lyophilized Hib component, and the combined vaccine administered to an individual child. The component vaccines should not be used separately.

- The lot numbers of the Pentacel components are linked so that the lot number of one component will identify the lot number of the other component. If Pentacel is used as supplied there is no need to record both numbers - the carton lot number or tear-off lot number label on the Hib vial (which are identical) is adequate and identifies all components. However, if the DTaP-IPV component is used to reconstitute a vial of ActHIB that is not supplied as Pentacel, both numbers should be recorded. Similarly, TriHIBit has a lot number for each of its two components, and there is no need to record both numbers when used as supplied.

If you have any questions or concerns please feel free to contact me at 605-773-5323 or by email at Tim.Heath@State.SD.US.

CY 2009 Provider Profile
South Dakota Childhood Immunization Program

This form must be completed for individual public and private facilities approved by the South Dakota Department of Health (DOH) for participation in the State Childhood Immunization Program. This document provides shipping information and is a guide for the State Immunization Program to determine the amount of vaccine to be supplied through the Program. The form may also be used to compare estimated vaccine needs with actual vaccine supply. The Immunization Program must keep this record on file with the *Provider Certification* form. *The Provider Profile* form must be updated annually or more frequently if estimates of children served changes (e.g. private provider becomes an agent of a Federally Qualified Health Center).

Facility / Provider Name **Provider Number**

Contact Person(s) Last First MI Title

Vaccine Delivery Address _____
(Street Address) Street City State Zip

Mailing Address _____
(if different) Street City State Zip

Telephone Number _____ Fax Number _____ Email _____

Special Shipping Instructions _____

A. Type of Facility (please check only one; see back for definitions)
☐ Public Health Department ☐ Private Practice ☐ Public Hospital
☐ Private Hospital ☐ Other Public ☐ Other Private

B. Is your facility a Rural Health Clinic (RHC) or a Federally Qualified Health Center (FQHC)?
☐ Yes ☐ No

C. For the 12-month period beginning 01/01/09, estimate the **number** doses you will be administering to children at your practice/clinic.

< 1 year old	**1-6 years**	**7-18 years**	**Total**
_____	_____	_____	_____

D. Of the totals entered above, how many doses are expected to be VFC doses because the child is:
Do not count the same doses in more than one category.

	< 1 year old	**1-6 years**	**7-18 years**	**Total**
Enrolled in Medicaid	_____	_____	_____	_____
Without Health Insurance	_____	_____	_____	_____
American Indian/Alaskan Native	_____	_____	_____	_____
Underinsured*	_____	_____	_____	_____

***Underinsured** – The patient has health insurance that does not cover vaccines.

E. **For Private Clinics only**: If your clinic works under another clinic, please give the clinic name:

_____

_____
Signature (person filling out this form) Date

Definitions:

Public Providers: Includes state, district, county, or city public health facilities where immunizations are administered. Also includes IHS clinics and IHS hospitals.

Private Providers: Individual or group private primary care or pediatric practices (includes also private practices in which some or all clients are members of managed care organizations).

CY 2009 Provider Certification
South Dakota Childhood Immunization Program

Facility Name _____ Provider Number_____

In order to participate in the State Childhood Immunization Program, I, on behalf of myself and any and all practitioners associated with this medical office, group practice, Health Maintenance Organization, health department, community/migrant/rural clinic, or other entity of which I am the physician-in chief or equivalent, agree to the following:

1. **Screen patients at all immunization encounters for eligibility and administer VFC-purchased vaccine only to children who 18 years of age or younger who meet one or more of the following categories:**
   a. **Is federally vaccine-eligible**
      (1) Is an American Indian or Alaska Native
      (2) Is enrolled in Medicaid
      (3) Has no health insurance
      (4) Is Underinsured: Children who have commercial (private) health insurance but the coverage does not include vaccines, children whose insurance covers only selected vaccines (VFC- eligible for non-covered vaccines only), or children whose insurance caps vaccine coverage at a certain amount-- once that coverage amount is reached, these children are categorized as underinsured. Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or Community Health Services (CHS). If the vaccine has universal status then the child does not need to be referred (please see most current vaccine eligibility chart).
   b. **Is considered State vaccine-eligible under criteria determined by South Dakota (e.g., underinsured children not served through a FQHC, RHC, or(CHS) for administration of pediatric vaccine purchased with 317 or other State funds.**

2. **Comply with immunization schedule, dosage, and contraindications that are established by the ACIP and included in the VFC program unless:**
   a. **In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate**
   b. **The particular requirements contradict state law, including those pertaining to religious and other exemptions**

3. **Maintain all records related to the VFC program for a minimum of three years and make these records available to public health officials including the state or Department of Health and Human Services (DHHS) upon request.**

4. **Immunize eligible children with VFC-supplied vaccine at no charge to the patient for the vaccine**.

5. **Not charge a vaccine administration fee that exceeds the administration fee cap of $13.56 per vaccine dose. For Medicaid VFC-eligible children, accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.**

6. **Not deny administration of a federally purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.**

7. **Distribute the most current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA) which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).**

8. **Comply with the requirements for ordering, vaccine accountability, and vaccine management. Agree to operate within the VFC program in a manner intended to avoid fraud and abuse.**

9. **The grantee or the provider may terminate this agreement at any time for personal reasons or failure to comply with these requirements. If the provider chooses to terminate the agreement, he or she agrees to properly return any unused VFC vaccine.**

10. **I agree to post, in a prominent clinic location, signage stating "Immunization records may now be shared without consent."**

11. **I will allow immunization clinic audits to be performed by the appropriate Department of Health staff. Acceptance of this requirement is acknowledgement of permission for these audits to be performed.**

12. **I will submit my Clinic Inventory and Doses Administered reports to the state by the 5th of each month. If I do not have the South Dakota Immunization Information System, I am required to submit a monthly Vaccine Administration Monthly Report (Form 05/2006) by the 5th of each month.**

13. **CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION: Consultant agrees that neither the Consultant, nor any of Consultant's principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in transactions by any Federal department or agency. Consultant will provide immediate written notice to the Department of Health, Division of Administration (600 East Capitol Avenue, Pierre, SD 57501 (605) 773-3361), if Consultant, or any of Consultant's principals, becomes debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in transactions involving Federal funding. Consultant further agrees that if this contract involves federal funds or federally mandated compliance, then Consultant is in compliance with all applicable regulations pursuant to Executive Order 12549, including Debarment and Suspension and Participants' Responsibilities, 29 C.F.R. § 98.510 (1990).**

Vaccine Management Requirements

Designate Vaccine Personnel

- Designate one staff member to be the primary vaccine coordinator and at least one back-up vaccine coordinator who is able to perform the same responsibilities as the primary vaccine coordinator in the event that the primary person is unavailable. These positions will be responsible for some key requirements and provide oversight for all vaccine management within the office.
- The designated vaccine coordinator and backup must be responsible for the following vaccine management activities:
    - ◦Adjusting the temperature of a vaccine storage unit
    - ◦Documenting the temperature on the temperature logs for each storage unit
    - ◦The primary vaccine coordinator should review temperature logs weekly if daily monitoring is being conducted by a backup person to ensure proper temperature recording. The backup staff should monitor the temperature logs if the primary coordinator is recording the daily temperatures.
- The primary and backup vaccine coordinators are responsible for training other staff that are responsible for administering vaccines or may be required to transport vaccine in an emergency situation based on the vaccine storage and handling plans. A simple log sheet with the staff member's name and date of training should be kept as documentation
- Unless otherwise noted, the vaccine coordinator and/or backup should be the VFC contacts for the office

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Storage and Handling Plans

- The routine vaccine storage and handling plan should include guidance on aspects of routine vaccine management which include:
    - ordering vaccines
    - controlling inventory
    - storing vaccines and monitoring storage conditions
    - minimizing vaccine wastage
    - vaccine shipping including receiving, packing and transporting
- The emergency vaccine storage and handling plan should include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions The emergency plan should include:
    - Person(s) responsible for preparing and transportation including contact information
    - How this person will be notified that vaccine needs to be moved
    - Location that will receive vaccine
    - How receiving location will be notified of transport
    - How to pack vaccine for transport
    - Worksheet to document vaccine involved in power or equipment failure

  At a minimum the emergency plan must be reviewed and updated (as necessary) on an annual basis or when there is a change in staff that has responsibilities in the emergency plan.

Vaccine Storage Equipment

- Two types of storage units are acceptable: 1) a refrigerator that has a separate freezer compartment with a separate exterior door or; 2) stand-alone refrigerators and freezers. Thermometers must be certified.

    - The refrigerator(s)or freezer(s) used for vaccine storage must
        - be able to maintain required vaccine storage temperatures year-round;
        - be large enough to hold the year's largest inventory;
        - have a working thermometer certified in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards placed in a central area inside each storage compartment
        - be dedicated to the storage of vaccines (food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature)

Vaccine Storage Practices

- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine
- Notify the immunization program of any vaccine doses that will expire before they can be administered. Only under the approval and direct guidance of the state, and only if the cold chain can be assured, redistribute short-dated vaccines to high-volume providers who are able to administer it before it expires
- Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas
- Properly space stored vaccine to allow for cold air circulation around the vaccine
- Do not store vaccines in the door of the storage unit

Temperature Monitoring

- Post a temperature log on the vaccine storage unit door or nearby and readily accessible
- Record refrigerator and freezer temperatures twice each day (beginning and end) ensuring that refrigerator temperatures are between 35° – 46° F (2° – 8°C). The freezer temperature should be <5°F (<-15°C); Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used
- Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges and document actions taken on the temperature log
- Maintain an ongoing file of temperature logs, and store completed logs for three years

Vaccine Shipments

- Immediately check vaccine cold chain monitors[1] and document the temperature inside the transport unit when vaccine arrives at office or clinic
- Take proper action if cold chain monitor was activated
- Develop a policy, complete with protocols and procedures, for maintaining the vaccine cold chain during transport to off-site clinics or emergency storage locations.

Vaccine Wastage

- Notify the immunization program of vaccine cold chain failure/wastage incidents involving publicly funded vaccines promptly after discovery of the incident. Follow the guidance of the state on how to document and report the incident.
- Implement written procedures to report and respond to losses resulting from vaccine expiration, wastage, and compromised cold chain
- Keep vaccine wastage below 5%. Wastage approaching 5% may result in an unannounced clinic audit by appropriate Department of Health staff. Vaccine wastage exceeding 5% may result in the removal of the agency/provider from the South Dakota Immunization Program.
- Remove wasted/expired vaccine from viable vaccine storage to prevent inadvertent administration.

[1] Cold Chain Monitors (CCMs) - These single-use devices come in three basic types: those that indicate whether packages have reached temperatures that are too warm, those that indicate whether packages have reached temperatures that are too cold, and those that continuously record the temperature. These types of monitors are designed to be irreversible indicators of inappropriate temperatures.

- All providers are allowed one excused episode of vaccine wastage due to "provider negligence". After that one time, any vaccine wastage may result in the provider being charged for the damaged vaccine. The provider will receive an invoice for the wasted vaccine. The invoice will reflect the CDC contract cost of the vaccine, minus the excise tax. Reimbursement for the cost of the vaccine wasted shall be due 30 days from the date of the invoice, and the provider will not receive any vaccine until the wastage has been resolved. Wastage reimbursement must be sent to the Immunization program and may occur through one of the following methods: A check made out to SDDOH, for the invoiced amount of wasted vaccine, **OR** A like amount of vaccine may be privately purchased to replace the wasted vaccine. Send a copy of the invoice for the purchased vaccine.
- Return, as directed by the grantee, all spoiled or expired publicly purchased vaccines for excise tax credit
    - Prior to implementation of centralized distribution, providers should return spoiled/expired vaccine to the grantee
    - Following implementation of centralized distributors, providers should return vaccine to the centralized distributor

Vaccine Preparation

- It is not acceptable clinical practice to pre-draw vaccines into syringes. Providers should draw vaccine only at the time of administration to ensure that the cold chain is maintained and the vaccine is not inappropriately exposed to light.

Vaccine Ordering and Inventory Management

- Order vaccine in accordance with actual vaccine need; avoid stockpiling or build-up of excess vaccine inventory
- Develop and maintain complete, accurate and separate stock records for both public and private vaccines. The requirement to keep separate records does not necessitate having separate storage units for public and private vaccines. Providers must be able to physically distinguish between their public and private vaccine stock.

Vaccine Security & Equipment Maintenance

- Post warning notices at both the electrical outlet and at the circuit breaker to prevent power from being disconnected

*It is now a requirement that **all** practitioners within an enrolled facility be listed on this form if they order the administration of childhood vaccines. Please list each practitioner on the lines provided. One physician is required to sign the "Provider Certification" form on behalf of all staff within the facility who are involved with immunizations.

Please Print

PHYSICIAN NAME (Last, First, Middle Initial)	**TITLE** (MD, DO, Etc)	**AREA OF SPECIALTY** (Peds, Family Medicine, Etc.)	**MEDICAL LICENSE #**	**MEDICAID PROVIDER #**

It is also required that **all** persons ADMINISTERING vaccines under the supervision of a prescribing VFC Provider (those enrolled above) be listed:

NAME (Last name, First Name, Middle Initial)	**TITLE** (R.N., L.P.N., etc.)	**SOUTH DAKOTA LICENSE NUMBER**

The original of this record must be submitted to and kept on file with the Immunization Program, South Dakota Department of Health, and must be updated annually in accordance with state policy.

Physician Name (printed) _____

Medical License Number_____ Medicaid Provider Number _____

Physician Signature _____

(2009)

STATE CHILDHOOD IMMUNIZATION PROGRAM
VACCINE ELIGIBILITY CHART

Vaccine	Those eligible for State-supplied Vaccine
DTaP (diphtheria/tetanus/acellular pertussis)	**All children under 7 years of age.**
DT (diphtheria/tetanus)	**All children under 7 years of age with contraindications for pertussis.**
Pediarix (diphtheria, tetanus, acellular pertussis, inactivated polio, and hepatitis B)	**All VFC eligible children under 7 years of age.* Pediarix is approved for first three doses of DTaP and IPV series only.**
Td (tetanus/diphtheria)	**All children 7 years through 10 years of age.**
Tdap	**All children 11 and 12 years of age. May also be given to VFC-Eligible children 11 through 18 years of age.***
Hib (Haemophilus Influenza B)	**All children under 5 years of age for first three doses. The 4th dose is limited to high risk children: children with asplenia, sickle cell disease, human immunodeficiency virus infection, and certain other immunodeficiency syndromes, and malignant neoplasms, and American Indian/Alaskan Native children.**
Pentacel (diphtheria, tetanus, acellular pertussis, Hib, and inactivated polio	**All children under 5 years of age for first three doses. The 4th dose is limited to high risk children: children with asplenia, sickle cell disease, human immunodeficiency virus infection, and certain other immunodeficiency syndromes, and malignant neoplasms, and American Indian/Alaskan Native children.**
DTaP-Hib (combination vaccine)	**Unavailable.**
IPV (inactivated polio vaccine)	**All children 2 months through 18 years of age.**
MMR (measles/mumps/rubella)	**All children 12 months through 18 years of age.**
Hepatitis B	**All children-birth through 18 years of age. If the series is started at age 18 the patient may finish series at age 19.**
Hepatitis A	**All VFC-Eligible children 12 months through 18 years of age.* The two doses in the series should be administered at least 6 months apart.**
PCV7 (Prevnar)	**All children under 5 years of age.**
Varicella (chicken pox)	**All children 12 to 15 months and 4 to 6 years of age. May also be given to VFC-eligible children 12 months through 18 years of age. ***
Meningococcal (MCV4)	**All VFC-eligible children 11 through 18 years of age.***
Rotavirus	**All VFC-eligible age appropriate children.***
Human Papillomavirus (HPV)	**All SD females 12 years of age. All VFC-eligible females 11 through 18 years of age. * All SD females 11-18 years of age that began the series in 2007 can finish the series in 2008 with the free state provided vaccine. If the patient turns 19 before finishing the series she can also finish the series with the free state provided vaccine.**
Influenza	**All children 6 months through 18 years of age.**

*** VFC-Underinsured need to receive their immunization at a FQHC/RHC/CHN facility. Non-VFC children will need to receive "privately purchased" vaccine.** Revised 11/05/2008

SOUTH DAKOTA DEPARTMENT OF HEALTH
REQUISITION FOR SHIPMENT OF BIOLOGICALS

Provider Name: _____ **Check if adding new provider information** ☐

Shipping Address: _____

Provider Number (REQUIRED): _____ _____

Telephone #: _____ Contact Person: _____

DESCRIPTION OF ARTICLE	Minimum Quantity Available For Order	QUANTITY- in *doses* only
Diphtheria-Tetanus (DT) (Pediatric)	10	
Tetanus-Diphtheria (Td) (Children 7 through 10 years of age only)	10	
Tdap	10	
DTaP	10	
DTaP/Hib (4th dose only)	5	Not Available
EIPV (Enhanced Inactivated Poliovirus)	10 dose vial	
Hepatitis A (pediatric)	10	
Hepatitis B (pediatric & adolescent)	10	
Hib	5	
HPV vaccine	10	
Measles-Mumps-Rubella (MMR)	10	
Meningococcal (MCV4)	5	
Pediarix (DTaP-EIPV-Hepatitis B combination)	10	
Pentacel (DTaP-Hib-EIPV combination)	10	
Pneumococcal Conjugate	10	
Rotavirus Vaccine (RotaTeq by Merck) (Three dose series)	10	
Rotavirus Vaccine (Rotarix by GSK) (Two dose series)	10	
Varicella (chickenpox vaccine) ***Please allow up to 20 working days for delivery. *Varicella vaccine will be shipped to your facility directly from manufacturer.**	10	
PPD (Tuberculin Skin Test Antigen) - 10 dose vial For Public Health Offices Only	10	
PPD (Tuberculin Skin Test Antigen) - 50 dose vial For Public Health Offices Only	50	
WE CAN NO LONGER BREAK UP VACCINE ORDERS INTO SINGLE DOSES DUE TO FEDERAL GUIDELINES.		

(Doses requested may be adjusted by DOH Immunization Program)

Signature of Receiving Agent: _____ Date Received: _____

FORMS & VIS ORDER FORM

Provider Name: _____ **Provider Number (REQUIRED):** _____

DESCRIPTION OF ARTICLE	QUANTITY	DESCRIPTION OF ARTICLE	QUANTITY
DTaP VIS (50/pad)		Vaccine Adverse Event Reporting form	
Hepatitis A VIS (50/pad)		Certificate of Immunization	
Hepatitis B VIS (50/pad)		Vaccine Administration Record	
HIB VIS (50/pad)		Vaccine Order Forms	
HPV VIS (50/pad)		Monthly Doses Administered Report	
Influenza VIS (50/pad)		Ring Bound Charts	
Meningococcal VIS (50/pad)		Temperature Logs	
MMR VIS (50/pad)		Transfer Vaccine Form	
Pneumococcal VIS (50/pad)		Wastage Report Form	
Polio VIS (50/pad)		Immunization Cards	
Rotavirus VIS (50/pad)		SDIIS Reminder/Recall postcards (50/pkg)	
Td VIS (50/pad)		Gel Refrigerator Thermometer	
TdaP VIS (50/pad)		Gel Freezer Thermometer	
Varicella VIS (50/pad)		Dickson Recorder	
Your Baby's First Vaccines Multi VIS (50)		Red pens for Dickson Recorder (6/pkg)	
After the Shots… (50/pad)		4 inch Disks for Dickson Recorder (60/pkg)	

*Questions regarding vaccine order, please contact the Immunization Program – Phone 605-773-4963, **Fax 605-773-4113** (Rev. 10/08)

Hib Vaccine Shortage Talking Points
October 20, 2008

In December of 2007, Merck announced a recall of Hib vaccine and temporarily stopped selling the vaccine in the U.S. market as they changed manufacturing processes.

- On December 13, 2007, Merck & Co., Inc. announced a voluntary recall of certain lots of two *Haemophilus influenzae* type b (Hib) conjugate vaccines, PedvaxHIB® (monovalent Hib vaccine) and Comvax® (Hib/hepatitis B vaccine).
- In the U.S., there are two licensed manufacturers of Hib vaccine – Merck, who produces PedvaxHIB and Comvax, and sanofi pasteur, who produces Hib vaccine in combination with DTP and IPV vaccines (Pentacel: DTP/IPV/Hib and TriHiBit: DTaP/Hib).

At that time, the recommended vaccination schedule for all available Hib-containing vaccines consisted of a primary series administered beginning at age 2 months and a booster dose at age 12--15 months.

In response to the decrease in vaccine supply resulting from Merck's inability to supply Hib vaccine to the US market, CDC changed the recommendation for Hib vaccination to defer the booster dose given at 12 to 15 months because it was unlikely that there would be there would adequate supplies of vaccine to fully vaccinate all children with Hib vaccine. Further recommendations included:

- Provider should continue regular vaccination for infants under 12 months.
- Providers temporarily defer the routine Hib vaccine booster dose given at 12-15 months of age except for specific high-risk groups, who should continue to receive the full vaccination series and the booster dose.
- Children at increased risk for Hib include: children with sickle cell disease, leukemia and malignant neoplasms, HIV and certain other immunocompromising conditions, asplenia, as well as American Indian and Alaska Native children. Vaccinating these children with the full schedule including a booster dose is a high priority.
- Providers should register and track children in whom the booster dose is deferred to facilitate recalling them for vaccination when supply improves.

On October 17, 2008, Merck released a public statement that they will not return to the Hib vaccine market until mid-2009.

- Merck was anticipating returning to the U.S. Hib vaccine market during the fourth quarter of 2008.
- Additional manufacturing changes at Merck will require a regulatory filing with FDA.
- Merck now projects a return to the U.S. market during mid-2009 in the U.S.

At this time, CDC is not changing Hib vaccine recommendations, but CDC will closely monitor the Hib vaccine supply situation and will make appropriate recommendations if the need arises.

CDC will continue to work closely with sanofi pasteur as they review their current Hib vaccine supply and their capacity to serve the U.S. market of the next 6-8 months. At this time, sanofi pasteur is confident that they have sufficient hib doses (ActHIB and Pentacel) to cover the 3 dose series through mid 2009.

American Indian and Alaska Native children living in American Indian or Alaska Native communities will continue to be provided with PedvaxHIB from CDC's stockpile.

CDC will closely monitor the Hib vaccine supply situation and will make appropriate recommendations if the need arises.

Thus far, we have not yet seen an increase in disease because of deferral of the booster dose at 12 to 15 months.

- The incidence of invasive Hib disease has declined dramatically in the U. S., resulting from high Hib conjugate vaccine coverage levels.
- Currently, the incidence of invasive Hib disease in children less than 5 years of age is 0.21 per 100,000 representing a greater than 99% reduction in disease compared to the pre-vaccine incidence.
- Children have a cushion of protection against Hib infection because population or community immunity afforded high immunization coverage rates made possible by success of Hib vaccination program.
- We are not certain how long this indirect protection will last. It is very important to directly protect infants by timely vaccination with the three-dose primary series at 2, 4, and 6 months of age.

ACIP Provisional Recommendations for the Prevention of Rotavirus Gastroenteritis among Infants and Children

Date of ACIP vote: June 25, 2008
Date of posting of provisional recommendations: July 1, 2008

A new rotavirus vaccine [Rotarix® (GlaxoSmithKline Biologicals)] was licensed on April 3, 2008 for use in the United States. On June 25, 2008, the ACIP voted on new recommendations for the use of rotavirus vaccine for the prevention of rotavirus gastroenteritis among infants and children.

The new provisional recommendations for the use of rotavirus vaccine follow:

Routine Administration

- For routine vaccination of US infants, two different rotavirus vaccine products are licensed: RotaTeq® (Merck & Co) (RV5) and Rotarix® (GSK) (RV1). The products differ in composition and schedule of administration. ACIP does not express a preference for RV5 or RV1.
- RV5 is to be administered orally in a 3-dose series with doses given at ages 2, 4, and 6 months. RV1 is to be administered orally in a 2-dose series with doses given at ages 2 and 4 months. The first dose of rotavirus vaccine should be administered from age 6 weeks through age 14 weeks 6 days (the maximum age for the first dose is 14 weeks 6 days). Vaccination should not be initiated for infants of age 15 weeks 0 days or older. The minimum interval between doses of rotavirus vaccine is 4 weeks. All doses should be administered by age 8 months 0 days.

Interchangeability of Rotavirus Vaccines

- ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. However, vaccination should not be deferred if the product used for previous doses is not available or is unknown. In this situation, the provider should continue or complete the series with the product available.
- If any dose in the series was RV5 or the product is unknown for any dose in the series, a total of three doses of rotavirus vaccine should be given.

Contraindications

- Rotavirus vaccine should not be administered to infants who have a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of rotavirus vaccine or to a vaccine component. Latex rubber is contained in the RV1 oral applicator, so infants with a severe (anaphylactic) allergy to latex should not receive RV1. The RV5 dosing tube is latex-free.

The 2006 ACIP recommendations for the prevention of rotavirus gastroenteritis among infants and children are available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5512a1.htm

The Rotarix® package insert is available at http://www.fda.gov/cber/label/rotarixLB.pdf

This document can be found on the CDC website at:
http://www.cdc.gov/vaccines/recs/provisional/downloads/roto-7-1-08-508.pdf